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EXAMINER	
LLOYD, EMILY M	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,552	SHIN ET AL.	
	Examiner	Art Unit	
	Emily M. Lloyd	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/22/2004, 06/29/2004, 07/19/2005.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because line 4 should have the word "the" after the word "of". Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: the first paragraph of the specification should be a section titled "Cross-Reference to Related Applications" and should include the a reference to the foreign priority claimed as well as the incorporation by reference material currently in paragraph [0041], paragraph [0042] line 5 should say channels instead of channel, the last line of paragraph [0045] should say was instead of is, paragraph [0046] lines 9-11 should be revised for clarity, paragraph [0048] lines 1-3 should be revised for clarity, paragraph [0050] line 4 should say "instead of" instead of than, and paragraph [0053] line 5 should have the word "out" deleted.

Appropriate correction is required.

Claim Objections

3. Claim 4 is objected to because of the following informalities: line 1 is missing the word "electrode" after multi-channel. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 11 is rejected because an analysis software system

is non-statutory subject matter as it is not a process, machine, manufacture, or composition of matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-2 and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Publication 2002/0062090 (Chai et al.).

Regarding claim 1, Chai et al. disclose an apparatus for measuring local skin impedance comprising: a multi-channel electrode (electrode array [0025] line 1) including a plurality of measurement sensors (discrete geometry electrodes 200 Figure 2A) on an electrode surface having a predetermined area (non-conductive surface 320 Figure 2B which has a predetermined area); a channel selector for selecting each of channels included in the multi-channel electrode in response to a channel control signal

([0018] lines 6-13); a constant current source for applying a predetermined constant current to a region to be measured (constant current source 10 Figure 1); a preprocessing unit (voltage drop measuring device 70 Figure 1) for amplifying (differential amplifier 80 Figure 1) and filtering (low pass filter (LPF) 100 Figure 1) a potential value measured at each of the channels while the predetermined constant current is flowing through the region to be measured; an analog-to-digital converter for converting the potential value output from the preprocessing unit into a digital signal (analog-to-digital converter 110 Figure 1); and a control unit for generating the channel control signal, for processing the digital signal output from the analog-to-digital converter, and for controlling the entire apparatus (microprocessor control unit (MCU) 120 Figure 1).

Regarding claim 2, Chai et al. disclose that the plurality of measurement sensors is arranged in a matrix shape on the electrode surface (electrode array [0025] line 1, see also Figures 2A and 2B).

Regarding claim 7, Chai et al. disclose that the constant current source comprises: a positive electrode (electrode array group 250 Figure 2A) and a negative electrode (electrode array group 260 Figure 2A), which are attached to a location on skin centering around the region to be measured such that the positive and negative electrodes are separated from the region to be measured by a predetermined distance (distance between electrode array group 250 and electrode array group 260 on non-conductive surface 320, Figures 2A and 2B), and the predetermined constant current output from the constant current source is applied to the skin through the positive

electrode, then output from the skin through the negative electrode, and then flows back in the constant current source (Figure 1).

Regarding claim 8, Chai et al. disclose that the preprocessing unit comprises: a differential amplifier (differential amplifier 80 Figure 1); and a filter (low pass filter (LPF) 100 Figure 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chai et al.

Chai et al. disclose the use of a low pass filter (low pass filter (LPF) 100 Figure 1). Chai et al. does not disclose the specific cut-off frequency or the specific type of filter. However, a Butterworth filter with a cutoff frequency of 4 Hz is a well-known low pass filter. Applicant has not disclosed that having the cutoff frequency at any specific number of Hertz within the low filter range and the filter being a Butterworth filter solves any stated problem or is for any particular purpose. Moreover, it appears that the filter of Chai et al., or applicant's invention, would perform equally well with a low pass filter with a different low frequency cutoff and a different low pass filter type.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Chai et al. such that the cutoff frequency was set at 4 Hz or less and the filter was a Butterworth filter because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Chai et al.

11. Claims 12-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mapping Acupuncture Points Using Multi Channel Device (Kwok et al.) in view of United States Patent Application 2001/0034491 (Benson et al.).

Regarding claim 12, Kwok et al. disclose a method of acquiring a local skin impedance (Method heading in left column of page 69, skin resistance map Figure 4 page 72), comprising: (a) measuring skin resistance during steady electrical conditions

for a predetermined time period (120 seconds, page 69 Method paragraph 1 line 16); (b) positioning a multi-channel electrode parallel to the region to be measured (Figure 3 page 71) and adjusting a measurement pressure (page 69 Hardware Design paragraph 1 lines 6-8); and (c) measuring skin impedance at the region to be measured (page 69 Hardware Design paragraph 1 lines 25-30 and line 36).

Kwok et al. disclose the claimed invention except for the steps of (a) disposing two electrodes of a constant current source centering around a region to be measured on a patient's skin to be separated from the region to be measured by a predetermined distance and applying a predetermined constant current to the skin through the two electrodes; and (c) applying the predetermined constant current between the two electrodes of the constant current source and measuring impedance while the predetermined constant current is being applied. Benson et al. teach the use of the steps of (a) disposing two electrodes of a constant current source centering around a region to be measured on a patient's skin (electrodes A and D, Figures 1 and 2, and constant current generation circuit 12 Figure 2) to be separated from the region to be measured by a predetermined distance (electrodes B and C are measured and are at predetermined distances from electrodes A and D, Figures 1 and 2) and applying a predetermined constant current to the skin through the two electrodes ([0032] lines 10-13); and (c) applying the predetermined constant current between the two electrodes of the constant current source ([0032] lines 10-13) and measuring impedance while the predetermined constant current is being applied ([0032] lines 13-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made

to use such steps of (a) disposing two electrodes of a constant current source centering around a region to be measured on a patient's skin to be separated from the region to be measured by a predetermined distance and applying a predetermined constant current to the skin through the two electrodes; and (c) applying the predetermined constant current between the two electrodes of the constant current source and measuring impedance while the predetermined constant current is being applied as taught by Benson et al. to measure skin impedance in the invention of Kwok et al. because this would provide a well known alternative to measure impedance with Ohm's Law.

Regarding claim 13, Kwok et al. as modified by Benson et al. disclose that the multi-channel electrode comprises: a plurality of measurement sensors arranged in a matrix shape on an electrode surface having a predetermined area (Kwok et al. "precise 16x16 square grid pattern" page 69 Method paragraph 1 line 2 and "8 cm by 8 cm" page 69 Hardware Design paragraph 1 line 6).

Regarding claim 14, Kwok et al. as modified by Benson et al. disclose that the measurement pressure is adjusted depending on a curvature of the region to be measured during measurement of skin impedance (Kwok et al. page 69 Method paragraph 1 lines 2-5).

Regarding claim 17, Kwok et al. as modified by Benson et al. disclose a computer readable medium having embodied therein a computer program (Kwok et al. "computer software developed for the probe" page 70 Software Design paragraph 1 line

4 on a PC page 70 Software Design paragraph 1 line 19) for the method of claim 12 (see 103 rejection of claim 12 above).

Regarding claim 18, Kwok et al. as modified by Benson et al. disclose a computer readable medium having embodied therein a computer program (Kwok et al. "computer software developed for the probe" page 70 Software Design paragraph 1 line 4 on a PC page 70 Software Design paragraph 1 line 19) for the method of claim 14 (see 103 rejections of claims 12 and 14 above).

12. Claims 1-2, 4-5, 7, 10-11, 15-16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwok et al. in view of Benson et al. as applied to claims 12-14 and 17-18 above, and further in view of Chai et al.

Regarding claim 1, Kwok et al. as modified by Benson et al. discloses an apparatus for measuring local skin impedance, comprising: a multi-channel electrode (Kwok et al. multi-channel probe page 36 Hardware Design paragraph 1 line 1) including a plurality of measurement sensors (Kwok et al. flat-ended pin acting as an electrode page 69 Hardware Design paragraph 1 line 3) on an electrode surface (Kwok et al. electrode array page 69 Hardware Design paragraph 1 line 4) having a predetermined area (Kwok et al. 8 cm by 8 cm page 69 Hardware Design paragraph 1 line 6); a channel selector (Kwok et al. multiplexers page 69 Hardware Design paragraph 1 lines 9-23) for selecting each of channels included in the multi-channel electrode in response to a channel control signal (Kwok et al. page 70 Software Design paragraph 1 lines 12-13); a constant current source for applying a predetermined constant current to a region to be measured (Benson et al. constant current generation

circuit 12 Figure 2 and [0032] lines 10-13); a preprocessing unit for filtering a potential value measured at each of the channels while the predetermined constant current is flowing through the region to be measured (Kwok et al. page 69 Method paragraph 2 line 4); an analog-to-digital converter for converting the potential value output from the preprocessing unit into a digital signal (Kwok et al. page 70 Software Design paragraph 1 line 14); and a control unit for generating the channel control signal, for processing the digital signal output from the analog-to-digital converter, and for controlling the entire apparatus (Kwok et al. PC (page 70 Software Design paragraph 1 line 19) running computer software (page 70 Software Design paragraph 1 lines 4-5 and lins 12-16), see also page 69 Method paragraph 2 lines 1-6).

Kwok et al. as modified by Benson et al. disclose the claimed invention except for an amplifier. Chai et al. teach the use of an amplifier (differential amplifier 80 Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such an amplifier as taught by Chai et al. to amplify the signals in the invention of Kwok et al. as modified by Benson et al. because it is well known in the art to amplify electrical signals.

Regarding claim 2, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the plurality of measurement sensors is arranged in a matrix shape on the electrode surface (Kwok et al. "precise 16 x 16 square grid pattern" page 69 Method paragraph 1 line 2).

Regarding claim 4, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the multi-channel further comprises twenty-five (25) measurement sensors

arranged in a 5x5 matrix (Kwok et al. a 5x5 matrix is comprised in a 16x16 matrix, page 69 Method paragraph 1 line 2).

Regarding claim 5, Kwok et al. as modified by Benson et al. and Chai et al. disclose that a pressure applied to each of the measurement sensors is adjusted depending on a curvature of the region to be measured during measurement of skin impedance (Kwok et al. page 69 Method paragraph 1 lines 2-5).

Regarding claim 7, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the constant current source comprises: a positive electrode and a negative electrode (Benson et al. electrodes A and D, Figures 1 and 2), which are attached to a location on skin (Benson et al. [0032] lines 10-13) centering around the region to be measured (Benson et al. electrodes B and C are centered between electrodes A and D, Figure 1, see also [0032] lines 13-16) such that the positive and negative electrodes are separated from the region to be measured by a predetermined distance (Benson et al. distances between electrodes in Figure 1), and the predetermined constant current output from the constant current source is applied to the skin through the positive electrode, then output from the skin through the negative electrode, and then flows back in the constant current source.

Regarding claim 10, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the control unit comprises: a personal computer for controlling the apparatus (Kwok et al. PC page 70 Software Design paragraph 1 line 19); and a signal processor for generating the channel control signal and expressing the potential values acquired at each of the channels of the multi-channel electrode (Kwok et al. page 70

Software Design paragraph 1 lines 22-24) as a two-dimensional impedance distribution and a three-dimensional impedance distribution under a control of the personal computer (Kwok et al. Figure 4 is a two-dimension impedance distribution, which shows the same data displayed in a three-dimensional impedance distribution with the degree of shading representing the third axis orthogonal to the paper. The data values used to represent the shading in a two-dimensional distribution are the same values used to represent the three-dimensional curves and shading on a three-dimensional impedance distribution. It would have been obvious to display the data used in the two-dimensional distribution of Figure 4 of Kwok et al. in a three-dimensional distribution because different plots give people different views (and thus highlight different aspects) of the same data).

Regarding claim 11, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the signal processor is an analysis software system (Kwok et al. "computer software developed for the probe" page 70 Software Design paragraph 1 line 4), which makes it possible to perform a measurement generally performed by an instrument such as an oscilloscope using the personal computer (Kwok et al. page 70 Software Design paragraph 1 lines 22-24).

Regarding claim 15, Kwok et al. as modified by Benson et al. and Chai et al. disclose a method of measuring local skin impedance (Kwok et al. Method heading in left column of page 69, skin resistance map Figure 4 page 72), comprising: measuring a potential value (Kwok et al. page 69 Method paragraph 1 lines 10-14) at each of a plurality of channels (Kwok et al. "all 256 pins" page 69 Method paragraph 1 line 16)

included in a multi-channel electrode (Kwok et al. multi-channel probe" page 69 Hardware Design paragraph 1 line 1) disposed between two electrodes of a constant current source for applying a predetermined constant current to a patient's skin through the two electrodes (Benson et al. electrodes A and D, Figures 1 and 2, and constant current generation circuit 12 Figure 2); amplifying (Chai et al. differential amplifier 80 Figure 1) and filtering the potential value at each channel (Kwok et al. page 69 Method paragraph 2 line 4); converting the filtered potential value from an analog format into a digital format (Kwok et al. page 70 Software Design paragraph 1 lines 13-16); and analyzing the potential value in the digital format and displaying the results of the analysis in a form of a spatial impedance distribution in two and three dimensions (Kwok et al. page 70 Software Design paragraph 1 lines 22-24 and paragraph 2 lines 1-12, also Figure 4, additionally see the discussion of spatial impedance distributions in different dimensions in the 103 rejection of claim 10 above).

Regarding claim 16, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the multi-channel electrode comprises: a plurality of measurement sensors arranged in a matrix shape on an electrode surface having a predetermined area (Kwok et al. "precise 16x16 square grid pattern" page 69 Method paragraph 1 line 2 and "8 cm by 8 cm" page 69 Hardware Design paragraph 1 line 6).

Regarding claim 19, Kwok et al. as modified by Benson et al. and Chai et al. disclose a computer readable medium having embodied therein a computer program (Kwok et al. "computer software developed for the probe" page 70 Software Design

paragraph 1 line 4 on a PC page 70 Software Design paragraph 1 line 19) for the method of claim 16 (see 103 rejection of claim 16 above).

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwok et al. in view of Benson et al. and Chai et al. as applied to claims 1-2, 4-5, and 7-19 above, and further in view of Multielectrode Surface EMG For Noninvasive Estimation of Motor Unit Size (Sun et al.).

Regarding claim 3, Kwok et al. as modified by Benson et al. and Chai et al. disclose that the measurement sensors are pin electrodes made of a metal conductor (Kwok et al. "stainless steel flat-ended pin acting as an electrode" page 69 Hardware Design paragraph 1 lines 2-3). Kwok et al. as modified by Benson et al. and Chai et al. do not disclose that the measurement sensors include a spring. Sun et al. teaches the use of measurement sensors that include a spring (Figure 1A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a spring in the measurement sensors as taught by Sun et al. to maintain constant contact and pressure with the area being measured in the invention of Kwok et al. as modified by Benson et al. and Chai et al. because this would "provide a cushion for obtaining a better contact between the probes and the skin surface." (Sun et al. page 1064 Methods paragraph 1 lines 8-10).

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwok et al. in view of Benson et al. and Chai et al. as applied to claims 1-2, 4-5, and 7-19 above, and further in view of The design and fabrication of a micro-thermal/pressure-sensor for medical electro-skin application (Ho).

Regarding claim 6, Kwok et al. as modified by Benson et al. and Chai et al. disclose the claimed invention except for the multi-channel electrode comprising a micro-electro-mechanical system (MEMS) electrode. Ho teaches the use of a micro-electro-mechanical system (MEMS) electrode (page 1205 Introduction paragraph 2 lines 1-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a micro-electro-mechanical system (MEMS) electrode as taught by Ho to take measurements in the invention of Kwok et al. as modified by Benson et al. and Chai et al. because this would make the device smaller and able to be used on smaller areas and to better pinpoint acupuncture points.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
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